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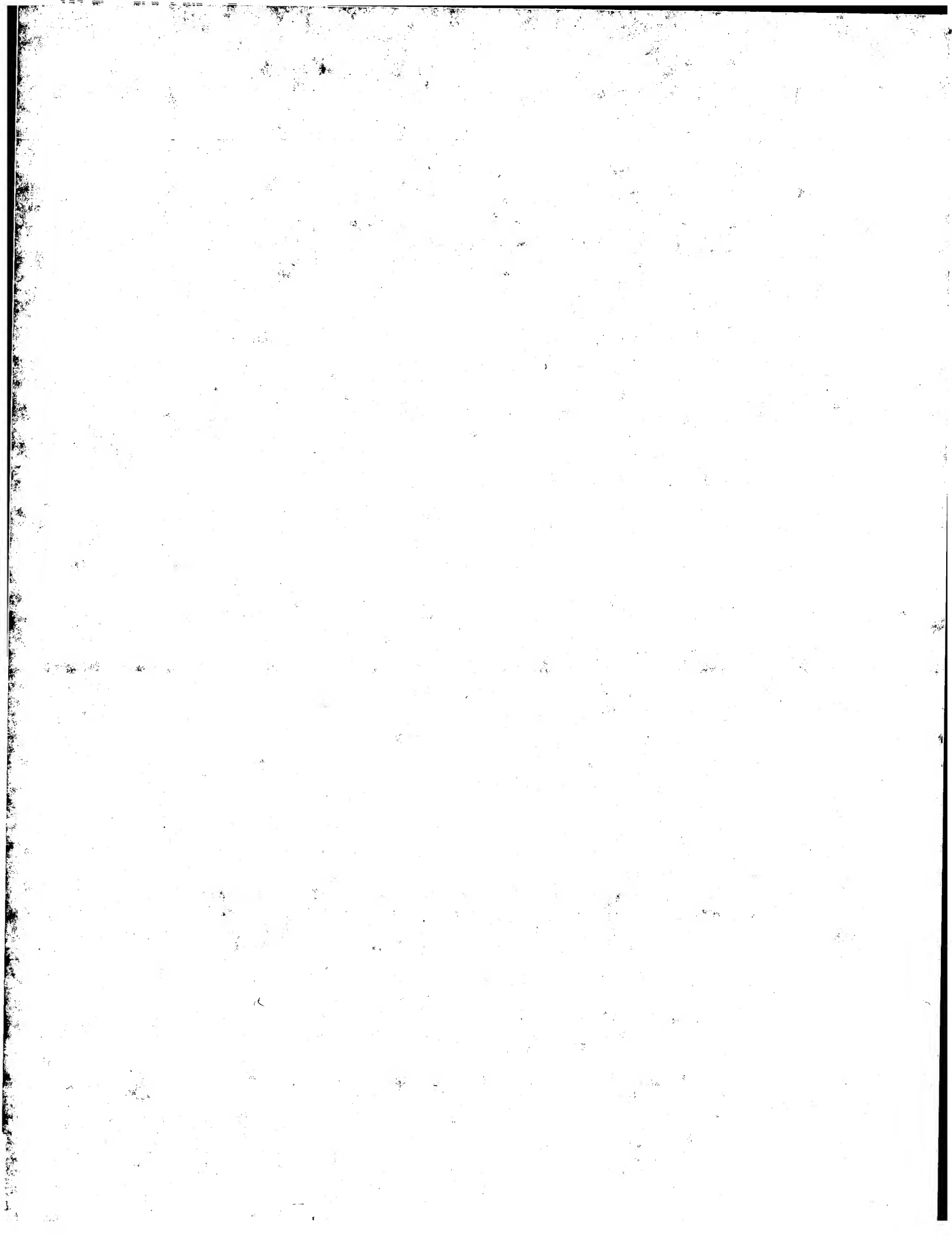
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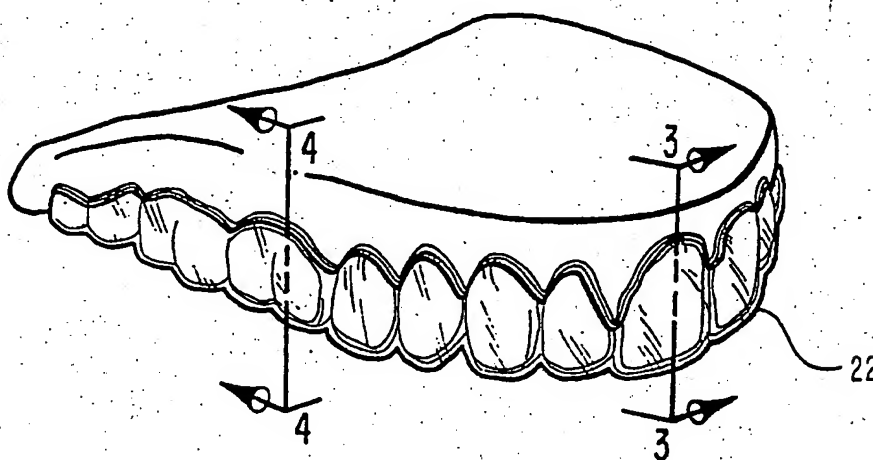
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES



## (57) Abstract

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray (22) having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

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DENTAL COMPOSITIONS AND METHODS  
FOR TREATING TEETH SURFACES

5

BACKGROUND

1. The Field of the Invention

10 The present invention relates to improved dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity dental compositions, such as tooth bleaching compositions, having significantly improved effectiveness and sustained release activity. The dental compositions may advantageously be used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

2. The Prior Art

20 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H<sub>2</sub>O<sub>2</sub>) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

30 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate

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1 impression of the patient's teeth; (2) making a stone cast  
of the impression; (3) vacuum forming a tray from the cast,  
usually from thin (0.020-0.030 inch) hard transparent  
5 material; (4) instructing the patient to (a) place 2-3  
drops of a bleaching solution into each area of each tooth  
to be bleached, (b) place the tray in the mouth, (3)  
expectorate any excess bleaching solution, (4) change the  
bleaching solution every 1 to 2.5 hours, and (5) remove the  
10 tray during meals. A few recommend wearing the tray during  
the night.

The most commonly used dental bleaching agent is 10%  
carbamide peroxide ( $\text{CO}(\text{NH}_2)_2\text{H}_2\text{O}_2$ ), also called urea hydrogen  
peroxide, hydrogen peroxide carbamide, and perhydrol-urea.  
15 Carbamide peroxide has been recommended and prescribed by  
dental clinicians since the 1960's as an oral antiseptic.  
Tooth bleaching was a side effect of extended usage. Over  
the counter ("OTC") compositions of 10% carbamide peroxide  
are available as "Gly-Oxide" by Marion Laboratories and  
20 "Proxigel" by Reed and Carnrick.

Positive results using the foregoing technique have  
been reported. The effectiveness depends upon such factors  
as type and intensity of stain, bleaching agent contact  
time on teeth, and amount of available active ingredient in  
the bleaching agent. Because the time commitment for the  
25 actual bleaching process takes place outside the dental  
office, the cost for the procedure is substantially less  
than conventional in-office bleaching techniques. More-  
over, patient discomfort associated with home-use tooth  
bleaching techniques both during and after treatment is  
30 reportedly less than that associated with conventional in-  
office bleaching.

Notwithstanding the foregoing advantages, there remain  
some important disadvantages to home-use bleaching products  
and techniques. One important disadvantage is that either  
35

1 the bleaching agent must be frequently replaced during the  
day or the treatment extend for several weeks or months.  
Clinical test results indicate that saliva dilution and  
5 swallowing of the bleaching agent caused the volume of  
agent in the tray to diminish rapidly over time, thereby  
decreasing the amount of active ingredient available for  
tooth bleaching. Test results show that after one hour,  
less than one-half the original volume of bleaching agent  
10 was present. Thus, existing bleaching agents should be  
replenished about every hour in order to be effective.

Since current home-use bleaching agents must be  
frequently replenished, the user necessarily ingests large  
volumes of the bleaching agent. In many cases, ingestion  
15 of the bleaching agent causes sore throats. Some  
researchers have even suggested that long term repeated  
ingestion of large quantities of carbamide peroxide may be  
carcinogenic. Therefore, patient ingestion of dental  
bleaching compositions should be minimized.

20 Many patient's daytime schedules do not permit them to  
constantly replenish the bleaching agent. In addition,  
even the suggestion of periodically replenishing the  
bleaching agent during the night would not be favorably  
received by most patient's. Because of the inconvenience  
25 of constantly replacing the dental agent, patient  
compliance is difficult to maintain, and since patient  
compliance determines the ultimate success of the  
treatment, the need to constantly replace the dental  
bleaching agent is a major inconvenience which limits the  
30 success of the treatment.

Another disadvantage with current home-use bleaching  
compositions and techniques is that it often takes weeks to  
see an observable result. Although some have reported  
lightening of teeth in shorter periods of time, in most  
35 cases the home-use bleaching treatment lasts from 4 to 6

1 weeks. Under such circumstances, patients often lose their  
enthusiasm for the procedure and often stop complying with  
the treatment regimen.

5 From the foregoing, it will be appreciated that what  
is needed in the art are improved compositions and methods  
for treating tooth surfaces which facilitate patient  
compliance, so that the ultimate purpose of the treatment  
is realized.

10 Additionally, it would be a significant advancement in  
the art to provide sustained release dental compositions  
for treating tooth surfaces which do not need to be  
continuously replaced so that patient compliance is  
enhanced.

15 It would be another significant advancement in the art  
to provide dental compositions for treating tooth surfaces  
which provide a more constant level of dental agent in  
contact with the teeth surfaces rather than periodic high  
and low levels of the dental agent in contact with the  
20 patient's teeth.

It would be an additional advancement in the art to  
provide dental compositions and methods for bleaching a  
patient's teeth which provide noticeable lightening in a  
matter of days rather than weeks.

25 Such dental compositions and methods for treating  
tooth surfaces are disclosed and claimed herein.

#### BRIEF SUMMARY AND OBJECTS OF THE INVENTION

30 The present invention is directed to high viscosity  
sustained release dental compositions, such as tooth  
bleaching or fluoride compositions, for treating tooth  
surfaces. An improved dental tray having reservoirs for  
holding the dental composition adjacent the desired tooth  
surfaces is preferably used in combination with the  
35 sustained release dental composition.



1 One currently preferred sustained release dental  
composition includes a dental bleaching agent, such as  
carbamide peroxide. The concentration of dental bleaching  
5 agent may vary depending upon its reactivity. For  
carbamide peroxide, for example, the currently preferred  
concentration range is from about 3% to about 20%, with a  
range from about 4% to about 15% being most preferred.

The dental bleaching agent is preferably included in  
10 a high viscosity matrix material to form the sustained  
release dental composition. Suitable matrix materials are  
preferably safe for oral use, do not readily dissolve in  
saliva, and do not react with the dental bleaching agent.  
One currently preferred high viscosity matrix material is  
15 a saturated carboxypolymethylene composition. A quantity  
of base is preferably added to the carboxypolymethylene  
composition to adjust the pH to within about 5.0 to about  
7.0.

The sustained release bleaching agents within the  
20 scope of the present invention have such a high viscosity  
that positive pressure is needed to dispense them, gravity  
is not sufficient. Unlike existing low-viscosity bleaching  
agents, the sustained release bleaching agents cannot be  
dispensed drop-wise from a bottle. A syringe, squeezable  
25 tube, or other similar positive pressure dispensing device  
must be used to dispense the bleaching compositions within  
the scope of the present invention.

An improved dental tray having reservoirs for holding  
the dental composition adjacent the desired tooth surfaces  
30 is preferably used in combination with the sustained  
release dental composition. The general process for  
preparing dental trays is known in the art. For example,  
an alginate impression which registers all teeth surfaces  
plus gingival margin is made and a stone cast is promptly  
made of the impression. The reservoirs are prepared by  
35

1 building a layer of rigid material on the stone cast on  
specific teeth surfaces to be treated. A dental tray is  
then vacuum formed from the modified cast using conven-  
5 tional techniques. Once formed, the tray is preferably  
trimmed barely shy of the gingival margin on both buccal  
and lingual surfaces. The resulting tray provides a  
perfect fit of the patient's teeth with reservoirs or  
spaces located where the rigid material was placed on the  
10 stone cast.

The reservoirs may also be creatively built into trays  
to provide additional bleaching agent to specific teeth or  
teeth surfaces which need more whitening than others. It  
has also been found that patients may experience less tooth  
15 discomfort from tray pressures when using a tray with built  
in reservoirs.

Before commencing a home-use teeth bleaching  
treatment, it is recommended that the patient's teeth be  
clean and that there be no restorations with leaky margins  
20 or exposed dentin. If there are large areas of exposed  
dentin or if restorations are inadequate, patients can  
develop mild to moderately severe pain.

The amount of whitening obtained during tooth  
bleaching is dependent upon (1) the length of time each day  
the tray is worn; (2) the number of days the tray is worn;  
25 and (3) the susceptibility of the teeth to the bleaching  
agent. For maximum whitening, an accelerated treatment  
time of approximately 18-20 hours per day is recommended.  
The treatment schedule may be tailored to each patient's  
30 lifestyle or response to the treatment, but will usually  
include at least treatment during the patient's sleep. It  
has been found that treatment during sleep is the most  
productive single treatment time of the day since less  
mouth activity "pumps" material from the tray.

1  
Recent experimental tests have compared one dental  
bleaching composition within the scope of the present  
invention with some commercially available dental bleaching  
5 compositions. All tested bleaching compositions had the  
same concentration of active ingredient (10% carbamide  
peroxide). The tests only examined bleaching effectiveness  
and did not consider increased effectiveness resulting from  
sustained release properties. The experimental results  
10 indicate that the present bleaching composition provides  
significantly greater effectiveness than the other tested  
bleaching compositions, irrespective of its sustained  
release properties. It is, therefore, an object of the  
present invention to provide highly effective dental  
15 bleaching compositions.

An additional object of the present invention is to  
provide improved compositions and methods for treating  
tooth surfaces which facilitate patient compliance, so that  
the ultimate purpose of the treatment is realized.

20 Another important object of the present invention is  
to provide sustained release dental compositions for  
treating tooth surfaces which do not need to be continu-  
ously replaced so that patient compliance is enhanced.

Yet another significant object of the present  
25 invention is to provide sustained release dental  
compositions for treating tooth surfaces which provide a  
more constant level of dental agent in contact with the  
teeth surfaces rather than periodic high and low levels of  
the dental agent in contact with the patient's teeth  
30 thereby providing noticeable lightening of a patient's  
teeth in a matter of days rather than weeks.

A further important object of the present invention is  
to provide an improved dental tray having built in  
reservoirs for holding dental compositions for treating

1 tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

2 These and other objects and features of the present  
5 invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 Figure 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

15 Figure 2 is a perspective view of the stone cast of Figure 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

Figure 3 is a cross-sectional view taken along line 3-3 of Figure 2.

Figure 3A is an enlarged cross-sectional view taken along line 3A-3A of Figure 3.

20 Figure 4 is a cross-sectional view taken along line 4-4 of Figure 2.

Figure 5 is a graph illustrating the results of Example 10.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is  
30 preferably used in combination with the sustained release dental composition.

35 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching

1 agent may vary depending upon its reactivity. For  
carbamide peroxide, for example, the currently preferred  
concentration range is from about 3% to about 20%, with a  
5 range from about 4% to about 15% being most preferred. In  
the case of hydrogen peroxide, which is more reactive than  
carbamide peroxide, the currently preferred concentration  
range is from about 2% to about 10%.

10 The dental bleaching agent is preferably included in  
a high viscosity matrix material to form the sustained  
release dental composition. Suitable matrix materials are  
preferably safe for oral use, do not readily dissolve in  
saliva, and do not react with or inactivate the dental  
bleaching agent. One currently preferred high viscosity  
15 matrix material is a concentrated carboxypolymethylene  
composition. Carboxypolymethylene is a slightly acidic  
vinyl polymer with active carboxyl groups. Suitable  
carboxypolymethylene compositions may be obtained from B.  
F. Goodrich Company under the trade name "carbopol".

20 The normal concentration of various  
carboxypolymethylene resins in water, according to the  
manufacturer, is below about 2%. Some commercially  
available dental bleaching compositions contain low  
concentrations of carbopol. Importantly, it has been found  
25 that by preparing saturated carboxypolymethylene  
compositions having an absolute concentration in the range  
from about 3.5% to about 12%, preferably from 4.5% to about  
10%, suitable high viscosity, sustained release dental  
compositions may be prepared.

30 Due to the large quantities of nonaqueous components  
in the dental compositions within the scope of the present  
invention, the actual concentration of carboxypolymethylene  
in the total quantity of water in the dental composition  
will preferably be in the range from about 15% to about  
35 35%, and most preferably from about 20% to about 30%. In

1 some special applications where very high concentrations of  
carboxy-polymethylene are desired, the concentration of  
carboxy-polymethylene in the total quantity of water in the  
5 dental composition may even be as great as about 40%.

One currently preferred carboxypolymethylene  
composition is known as Carbopol 934P. Carbopol 934P is a  
high purity pharmaceutical grade of Carbopol 934, having an  
approximate molecular weight of about 3,000,000. In  
10 addition to thickening, suspending, and emulsifying,  
Carbopol 934P has been used in dry tablets to impart  
sustained release properties. Extensive toxicity studies  
have been conducted on Carbopol 934P, and a master file has  
been established with the Food and Drug Administration. It  
15 is listed as Carbomer 934P in the National Formulary.

It is believed other carboxypolymethylene resins, such  
as Carbopol 940, may be substituted for the Carbopol 934P.  
However, based upon clinical and laboratory evaluations,  
Carbopol 940 appears to dilutes faster than Carbopol 934P.  
20 In addition, Carbopol 934P is currently preferred because  
it is obtainable in a pharmaceutical grade. Therefore,  
Carbopol 934P is a currently preferred carboxypolymethylene  
composition.

The concentrated carboxypolymethylene compositions  
25 within the scope of the present invention have a number of  
important characteristics in addition to high viscosity.  
Enough carboxypolymethylene is added to the dental  
compositions beyond that required to provide high viscosity  
such that a significant quantity of saliva or water is  
30 required to lower the viscosity to the point that the  
dental agent may be diluted and washed out by saliva.  
Because the high level of carboxypolymethylene makes  
dilution from saliva difficult and more time consuming, the  
resulting dental compositions provide a sustained release  
35 of the dental agent.

1           Another important advantage of the concentrated  
carboxypolymethylene compositions within the scope of the  
present invention is that on contact with saliva, the  
5       composition becomes initially firmer. As a result, a seal  
around the periphery of the dental tray is formed where the  
composition is in contact with saliva which keeps the  
remainder of the composition in contact with the teeth  
surfaces entrapped and "sealed" therein. The firmer  
10       material at the tray periphery also fills the minor  
discrepancies of the tray-to-tooth fit.

          In most cases, high levels of carboxypolymethylene  
will be preferred so that the sustained release action of  
the dental composition will be maintained over a greater  
15       period of time in a high salivating patient. However, in  
some cases it may be desirable to use lower concentrations  
of carboxypolymethylene, relatively speaking, but still  
higher than typical concentrations, so that the sustained  
release action will last a shorter period of time. Thus,  
20       by varying the concentration of carboxypolymethylene, some  
control over the period of dental agent activity may be  
obtained.

          The concentrated carboxypolymethylene composition also  
has a tackiness or stickiness which retains and seals the  
25       thin soft tray material against the teeth thereby  
preventing migration of the composition out of the tray.  
The tackiness of the composition not only keeps the  
composition within the reservoirs, but also retains the  
tray against the patient's teeth, thereby permitting  
30       softer, thinner, and more flexible tray materials to be  
used. It has been found that if too much  
carboxypolymethylene is used, the tackiness can decrease  
and the composition encumbers complete tray insertion.

          In order to obtain a concentrated carboxypolymethylene  
35       composition, it is recommended that the carboxypoly-

1 methylene be mixed with a quantity of glycerine before  
attempting to disperse it in water. The glycerine enables  
the large quantities of carboxypolymethylene to be  
5 dispersed easier in water. It has also been observed that  
once the carboxypolymethylene and glycerine are mixed, it  
is important to quickly disperse the mixture in the water  
or else it becomes an unmanageable solid. It is  
recommended that the concentration of glycerine in the  
10 final sustained release dental composition be in the range  
from about 20% to about 70% by weight, and preferably in  
the range from about 40% to about 60% by weight.

In addition to functioning as a humectant, the  
glycerine also provides some flavor sweetening enhancement  
15 such that a bland flavor is perceived. A few possible  
substitutes for glycerine include polypropylene, sorbitol,  
some polyethylene glycols or other polyols.

It is currently preferred that the amount of water in  
the sustained release dental composition be in the range  
20 from about 10% to about 60% by weight, and preferably in  
the range from about 15% to about 40% by weight. It will  
be appreciated that the quantity of water in the total  
dental composition may come from different sources. For  
instance, the dental bleaching agent and base, discussed  
25 below, may come as aqueous solutions.

Because carboxypolymethylene is a polycarboxylic acid,  
it tends to lower the pH of the resulting bleaching  
composition. It appears, based upon clinical and in vitro  
testing, that dental compositions with a pH below about 5  
30 are able to etch enamel. To avoid etching enamel, it is  
currently preferred to have the pH of the sustained release  
bleaching composition in the range from about 5 to about 7.  
This is most easily accomplished by adding a base to the  
composition to adjust the pH. Inorganic and organic bases  
35 may be used; the use concentrated sodium hydroxide (50%



1 NaOH) is one currently preferred embodiment. Although it  
is possible to use lower concentrations of sodium hydroxide  
or other bases, such as triethanolamine, there is a risk  
5 that the lower concentrations may dilute the dental  
composition and affect its viscosity or sustained release  
characteristics.

An important characteristic of the high viscosity,  
sustained release dental compositions within the scope of  
10 the present invention is that the compositions are still  
observed, from a clinical standpoint, after about 3 to 7  
hours of normal daytime activity and after about 7 to 10  
hours of sleep. That is, the sticky, high viscosity dental  
composition is still observable in the dental tray after an  
15 extended period of time, such as at the end of the night.

Unlike existing low-viscosity bleaching agents which  
are placed drop-by-drop into the tray, the sustained  
release bleaching agents within the scope of the present  
invention have such a high viscosity that they cannot be  
20 dispensed drop-wise into the tray from a bottle. Positive  
pressure is needed to expel the sustained release bleaching  
agents of the present invention, gravity is not sufficient.

One currently preferred method of dispensing the  
bleaching agent uses a syringe. Squeezable tubes and other  
25 similar dispensing devices may also be used to dispense the  
bleaching agent. Upon dispensing, the sustained release  
bleaching agent is sufficiently viscous that it does not  
settle or spread when dispensed, but remains as a single  
extruded strand of bleaching agent.

30 It is currently preferred to provide a unit dose of  
the dental agent in a syringe or similar dispensing device.  
In this way, the patient can load the precise amount of  
dental agent onto the dental tray for each treatment  
period. By using such dispensing devices, the dentist is

1 also able to monitor and control how many doses the patient  
has received and used.

5 An improved dental tray having reservoirs for holding  
the dental composition adjacent the desired tooth surfaces  
is preferably used in combination with the sustained  
release dental composition. The general process for  
preparing dental trays is known in the art. For example,  
10 an alginate impression which registers all teeth surfaces  
plus gingival margin is made and a stone cast is promptly  
made of the impression. Excess stone is trimmed away for  
ease of manipulation and forming of the plastic tray.

Reference is now made to Figures 1-4. The present  
invention modifies known procedure by applying a thin  
15 coating 10 of rigid material to stone cast 12 over the  
teeth surfaces to be treated. As shown in Figure 1,  
coating 10 may be conveniently applied using a syringe  
applicator 14. The coating may be also light cured for  
convenience. Care is taken to ensure that coating 10 is  
20 kept a distance greater than about 1 mm from gingival line  
16 and preferably kept from about 1 1/4 mm to about 1 1/2  
mm from gingival line 16. The finished coating is  
preferably about 1/2 mm thick. It is particularly  
important when applying the rigid coating material to not  
25 cover over incisal edges 18 and occlusal edges 20. These  
edges should contact the finished tray to prevent vertical  
movement of the tray during use which could act as a pump  
by expressing out the bleaching agent and sucking in  
saliva.

30 A dental tray 22 is then vacuum formed from the  
modified cast using conventional techniques. Tray 22 is  
preferably constructed of soft transparent vinyl material  
having a preformed thickness from about 0.035 inch to about  
0.06 inch. Soft material is more comfortable for the  
35 patient to wear. Most patient's will find 0.035 inch to be

1 suitable. It will be appreciated that the final tray  
thickness may vary depending on the technique used to  
prepare the tray. Patient's suspected of being bruxers or  
5 hard biters may require a 0.06 inch tray material. Of  
course, patients should be counselled to not eat with trays  
in place or to bite firmly into them. In extreme cases, a  
thicker or harder plastic may be necessary.

Once formed, tray 22 is preferably trimmed barely shy  
10 of gingival margin 16 on both buccal and lingual surfaces.  
Enough tray material should be left to assure that all of  
the tooth will be covered to within about 1/4 mm to about  
1/3 mm of the gingival border upon finishing and beveling  
of the tray periphery. It is also important to scallop up  
15 and around interdental papilla so that the finished tray  
does not cover them. All tray edges are preferably  
smoothed so that the lip and tongue will not feel an edge  
prominence. Slight adjustments to the tray may be made by  
carefully heating and stretching the tray material.

20 From practice, it has been found that patients may  
experience less tooth discomfort from tray pressures when  
using a tray with reservoirs built into the tray as  
described above. It is currently believed this is due to  
the fact that the teeth are not held as firmly by the tray,  
25 so "orthodontic" pressures experienced by teeth from tray  
indiscrepancies are minimized. The use of thin, soft tray  
materials further minimizes these "orthodontic" forces,  
compared to the harder plastics currently used in the art.

30 Reservoirs may also be creatively built into trays to  
provide additional bleaching agent to one or more teeth of  
an arch needing more whitening than others or to selected  
parts of a tooth needing more whitening than other parts.

To achieve most rapid results, it is recommended to  
use sustained release bleaching agent within the scope of  
35 the present invention in combination with the trays

1 incorporating reservoirs. Nevertheless, it has been  
observed that bleaching occurs much more rapidly using  
conventional trays with sustained release bleaching  
5 compositions of the present invention than with existing  
bleaching agents. In addition, some increase in  
effectiveness has also been observed when using existing  
bleaching agents with trays incorporating reservoirs than  
with conventional trays without reservoirs.

10 Before commencing a home-use teeth bleaching  
treatment, it is recommended that the patient's teeth be  
clean of calculus and external stains. Restorations should  
be water tight and all dentin, particularly gingival dentin  
with potential or existing sensitivities, should be  
15 covered. It has been observed that exposed root surfaces  
may experience sensitivity from sustained release bleaching  
agent within the scope of the present invention. In many  
cases dentin may be covered with a layer of dentin bonding  
agent or sealant to prevent this.

20 Since most patients will want to complete their  
treatment as soon as possible, recommended treatment times  
start at approximately 18-20 hours a day. Patients are  
instructed to insert the tray loaded with fresh bleaching  
agent after each meal and before going to bed for most  
25 rapid results. Gum soreness or other patient discomfort  
has been reported more often for such accelerated treatment  
schedules that go longer than one to two days.

A second possible treatment schedule is to allow a  
break-time to occur between dinner and bed. This allows  
30 the patient to participate in evening social functions  
without wearing the tray. In addition, oral tissues are  
allowed to rest during the break-time.

Another recommended treatment schedule, particularly  
for those where the treatment may require more than one or  
35 two days, is to load and insert the tray only before bed

1 and after lunch. This gives the teeth and soft tissues a  
rest for approximately two 4-5 hour intervals between the  
two longer treatment periods. Potential soreness is most  
5 often prevented this way and treatment time may only be  
extended 20% to 30% over the more accelerated treatment  
schedules.

Finally, for those patients who are often in public or  
those who have experienced moderate or greater problems of  
10 soreness, it is recommended that the tray be worn only at  
night. During sleep is the most productive single  
treatment time since less mouth activity "pumps" material  
from the tray.

Regardless of which treatment schedule is used, the  
15 use of sustained release dental bleaching compositions  
within the scope of the present invention provides a more  
constant level of bleaching agent adjacent the teeth than  
existing home-use bleaching systems. Even if patient  
compliance with existing home-use dental bleaching systems  
20 is such that fresh bleaching agent is added every hour,  
there still would be periodic high and low levels of  
bleaching agent adjacent the teeth. Since the amount and  
length of time the active bleaching agent is adjacent the  
teeth significantly influences the efficiency of the  
25 treatment, the sustained release bleaching compositions and  
methods of the present invention represent a significant  
improvement over existing home-use dental bleaching  
systems.

If patient instructions are followed, more predictable  
30 results are obtained in days rather than weeks. Also, less  
total volume of bleaching agent is used (from 1/10 to 1/20  
the volume of conventional peroxide solutions). As a  
result, less bleaching agent is swallowed by the patient.

At the end of the bleaching treatment, a sustained  
35 release fluoride composition may optionally be administered

1 to the patient. For convenience, the same tray may be used  
to treat the teeth with fluoride as was used to bleach the  
teeth. Such fluoride treatment regimens may include 2 to  
5 4 three hour treatments, or 1 or 2 night-time treatments.  
One typical sustained release fluoride composition within  
the scope of the present invention contains 0.5% sodium  
fluoride in a high viscosity gel.

The following examples set forth various sustained  
10 release dental compositions within the scope of the present  
invention. These examples are intended to be purely  
exemplary and should not be viewed as limiting the scope of  
the present invention.

15 EXAMPLE 1

A sustained release dental bleaching composition  
within the scope of the present invention was prepared by  
combining the following ingredients:

	<u>Ingredient</u>	<u>Weight</u>	<u>Weight %</u>
20	Carbamide peroxide	13.2 gm	10%
	Water	27.5 gm	21%
	Glycerine	74.6 gm	57%
	Carbopol 934P	9.5 gm	7%
	Sodium hydroxide (50%)	6.5 gm	5%

The Carbopol 934P was obtained from B.F. Goodrich Company,  
25 Cleveland, Ohio. The carbopol was combined with the  
glycerine and then quickly mixed with the water. The  
glycerine enables the carbopol to be dispersed in the  
water. The carbamide peroxide was dissolved in the water  
before the glycerine-carbopol mixture was added to the  
30 water. The foregoing composition had a percentage of  
carbopol in water of about 25.7%. The sodium hydroxide was  
gradually blended into the homogeneous composition in order  
to raise the pH to an acceptable level.

1       The foregoing procedure produced in a sustained  
release dental bleaching composition which was placed in a  
dental tray such as that described in connection with  
5       Figures 1-4 and worn by a patient for 9 hours. Subsequent  
examination of the patient's teeth indicated that the teeth  
had whitened 1-1.5 units on a Vita shade guide and that  
significant quantities of the sustained release bleaching  
composition was still observed in the application tray.

#### 10                   EXAMPLE 2

A sustained release dental bleaching composition  
within the scope of the present invention was made  
according to the procedure of Example 1, except that the  
15       ingredients were combined in the following amounts:

<u>Ingredient</u>	<u>Weight</u>	<u>Weight %</u>
Carbamide peroxide	1150	10
Water	2030	18
Glycerine	6660	59
Carbopol 934P	830	7
Sodium hydroxide	650	6

20       The foregoing procedure resulted in a sustained  
release dental bleaching composition. The foregoing  
composition has a percentage of carbopol in water of about  
25.6%. The composition possessed a high viscosity and  
25       excellent sustained release teeth bleaching activity.

#### EXAMPLE 3

A sustained release dental bleaching composition  
within the scope of the present invention is made according  
30       to the procedure of Example 1, except that the ingredients  
are combined in the following amounts:

<u>Ingredient</u>	<u>Weight Percent</u>
Carbamide peroxide	20
Water	20
Glycerine	40
35       Carbopol 934P	12

1 Sodium hydroxide 8

The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

#### EXAMPLE 4

10 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

	<u>Ingredient</u>	<u>Weight Percent</u>
15	Carbamide peroxide	5
	Water	20
	Glycerine	60
	Carbopol 934P	10
	Sodium hydroxide	5

The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

#### EXAMPLE 5

25 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

	<u>Ingredient</u>	<u>Weight Percent</u>
30	Carbamide peroxide	10
	Water	40
	Glycerine	30
	Carbopol 934P	12
	Sodium hydroxide	8

35



1       The foregoing procedure results in a sustained release  
dental bleaching composition. The foregoing composition  
has a percentage of carbopol in water of about 23.1%. The  
5       composition possesses a high viscosity and excellent  
sustained release teeth bleaching activity.

#### EXAMPLE 6

10       A sustained release dental bleaching composition  
within the scope of the present invention is made according  
to the procedure of Example 1, except that the ingredients  
are combined in the following amounts:

	<u>Ingredient</u>	<u>Weight Percent</u>
	Carbamide peroxide	18
	Water	15
15	Glycerine	60
	Carbopol 934P	4
	Sodium hydroxide	3

20       The foregoing procedure results in a sustained release  
dental bleaching composition. The foregoing composition  
has a percentage of carbopol in water of about 21.1%. The  
composition possesses a high viscosity and excellent  
sustained release teeth bleaching activity.

#### EXAMPLE 7

25       A sustained release dental bleaching composition  
within the scope of the present invention is made according  
to the procedure of Example 1, except that the ingredients  
are combined in the following amounts:

	<u>Ingredient</u>	<u>Weight Percent</u>
	Carbamide peroxide	14
30	Water	10
	Glycerine	70
	Carbopol 934P	3.5
	Sodium hydroxide	2.5

35       The foregoing procedure results in a sustained release  
dental bleaching composition. The foregoing composition

1 has a percentage of carbopol in water of about 25.9%. The  
composition possesses a high viscosity and excellent  
sustained release teeth bleaching activity.

#### 5 EXAMPLE 8

A sustained release dental bleaching composition  
within the scope of the present invention is made according  
to the procedure of Example 1, except that the ingredients  
10 are combined in the following amounts:

<u>Ingredient</u>	<u>Weight Percent</u>
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
15 Sodium hydroxide	5

The foregoing procedure results in a sustained release  
dental bleaching composition. The foregoing composition  
has a percentage of carbopol in water of about 14.3%. The  
composition possesses a high viscosity and excellent  
20 sustained release teeth bleaching activity.

#### EXAMPLE 9

A sustained release dental fluoride composition within  
the scope of the present invention was prepared by  
25 combining the following ingredients:

<u>Ingredient</u>	<u>Weight</u>	<u>Weight Percent</u>
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
30 Sodium hydroxide (50%)	238 gm	5.1%

The foregoing ingredients are mixed according to the  
procedure of example 1, except that sodium fluoride is used  
instead of carbamide peroxide. The fluoride concentration  
is preferably maintained about 1.1% so that the free  
35 fluoride ion concentration is about 0.5%. The foregoing

1 composition has a percentage of carbopol in water of about  
27.5%. The foregoing procedure produces a sustained  
release dental fluoride composition suitable for use with  
5 a dental tray such as that described in connection with  
Figures 1-4.

#### Example 10

10 In this example, the in vitro brightening effect of  
two commercially available bleaching agents was measured  
and compared with the dental bleaching composition prepared  
according to the procedure of Example 1. Thirty-six (36)  
extracted anterior and premolar teeth without caries or  
restorations were randomly divided into four (4) groups and  
15 mounted. A thermoplastic splint was made for each group.  
In addition to the dental bleaching agent of Example 1,  
Denta-Lite (manufactured by Challenge Products, Osage  
Beach, MO) and Proxigel (manufactured by Reed & Carnrick,  
Piscataway, New Jersey) were tested. All of bleaching  
20 agents contained 10% carbamide peroxide as the active  
ingredient. Groups 1-3 were treated with the bleaching  
agents and group 4 was used as a control and bathed in  
sterile distilled water.

25 Bleaching agent was placed into a splint and replaced  
every 3 hours during the day and after 8 hours at night.  
The treatment continued for a period of 2 weeks averaging  
a minimum of 18 hours of bleaching per day. All teeth and  
splints were brushed and rinsed with water before replacing  
bleaching agents.

30 Measurements were taken using a Pentax photo spot  
meter, measuring brightness changes occurring at intervals  
of 24 hours, 72 hours, 7 days, and 14 days. The photo spot  
meter was equipped with an analog meter and the ability to  
read in 0.1 value variations. The meter was attached to a  
35 measuring apparatus which reflected two light sources at a

1 60 degree deflection angle toward the crown of the tooth  
being measured. A rheostat controlled the light sources to  
allow a constant emittance during each measurement. The  
5 data were analyzed using a 2-way ANOVA and Duncan's  
multiple range test.

Photographs were taken before, at 72 hours, and at 14  
days following bleaching. A 35 mm single reflex camera  
with a macro lens and a 2x diopter was used for all  
10 photography.

The results of this Example are reported in Table 1  
and illustrated graphically in Figure 5. They indicate  
that the dental bleaching composition within the scope of  
the present invention is over 50% more effective than the  
15 two commercially available dental bleaching agents having  
the same concentration of active ingredient. In fact, the  
bleaching agent of Example 1 provided greater whitening in  
just 3 days of treatment than the other bleaching agents  
did after two weeks of treatment.

20 It is important to recognize that the results of this  
Example do not address the impact of saliva on the  
effectiveness of the dental bleaching agents. The  
sustained release characteristics of the dental bleaching  
agent within the scope of the present invention were not  
25 addressed by this Example. Therefore, the effectiveness of  
the present invention can be expected to be even greater  
than the prior art bleaching agents when the sustained  
release activity is considered.

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Table 1

Bleaching Effect of 10% Carbamide Peroxide  
Value Changes: Means and standard deviations

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Bleaching Agent	No.	24 Hrs.	72 Hrs.	7 Days	14 Days
Water	9	0	0	0	0
Example 1	9	.34(.06)	.56(.08)	.60(.09)	.67(.13)
Denta-Lite	9	.22(.08)	.35(.11)	.38(.10)	.48(.13)
Proxigel	9	.22(.07)	.33(.12)	.34(.11)	.40(.10)

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Although much of the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other dental compositions, whether sustained release or not, may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the such dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

30

35

In some cases, the dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained

1 release action may last from hours to days, depending on  
the patient's oral and salival activity.

5 From the foregoing, it will be appreciated the present  
invention provides improved compositions and methods for  
treating tooth surfaces which facilitate patient  
compliance, so that the ultimate purpose of the treatment  
is realized.

10 Additionally, it will be appreciated that the present  
invention further provides sustained release dental  
compositions for treating tooth surfaces which do not need  
to be continuously replaced so that patient compliance is  
enhanced. The present invention also provides sustained  
15 release dental compositions for treating tooth surfaces  
which permit a more constant level of the dental agent to  
be in contact with the teeth surfaces rather than periodic  
high and low levels of the dental agent in contact with the  
patient's teeth.

20 It will be further appreciated that the present  
invention provides dental compositions and methods for  
bleaching a patient's teeth which provide noticeable  
lightening in a matter of days rather than weeks.

25 In addition, it will be appreciated that the present  
invention provides an improved dental tray having built in  
reservoirs for holding dental compositions for treating  
tooth surfaces which enhance the effectiveness of the  
dental treatment and patient comfort.

30 The present invention may be embodied in other  
specific forms without departing from its spirit or  
essential characteristics. The described embodiments are  
to be considered in all respects only as illustrative and  
not restrictive. The scope of the invention is, therefore,  
indicated by the appended claims rather than by the  
foregoing description. All changes which come within the

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meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

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- 1           1.    A dental bleaching composition comprising:  
            a quantity of dental bleaching agent capable of  
bleaching vital tooth surfaces in contact with said  
5           dental bleaching agent; and  
            a matrix material into which the dental bleaching  
agent is dispersed, said matrix material including  
carboxypolymethylene in the range from about 3.5% to  
about 12% by weight of the dental bleaching  
10          composition.
2.    A dental bleaching composition as defined in  
claim 1, wherein the matrix material comprises  
carboxypolymethylene in the range from about 4.5% to about  
15          10% by weight of the dental bleaching composition.
3.    A dental bleaching composition as defined in  
claim 1, wherein the matrix material comprises  
carboxypolymethylene in the range from about 6% to about 8%  
20          by weight of the dental bleaching composition.
4.    A dental bleaching composition as defined in  
claim 1, wherein the matrix material comprises  
carboxypolymethylene in the range from about 15% to about  
25          35% by weight of the total quantity of water in the total  
dental bleaching composition.
5.    A dental bleaching composition as defined in  
claim 1, wherein the matrix material comprises  
30          carboxypolymethylene in the range from about 20% to about  
30% by weight of the total quantity of water in the total  
dental bleaching composition.
6.    A dental bleaching composition as defined in  
claim 1, further comprising a sufficient quantity of a base  
35



1 to adjust the pH of the dental bleaching composition to within the pH range from about 5 to about 7.

5 7. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

10 8. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

15 9. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises hydrogen peroxide in the range from about 2% to about 10% by weight of the dental bleaching composition.

20 10. A dental bleaching composition comprising:  
a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with said dental bleaching agent;  
a quantity of water having a weight percent of  
25 the total dental bleaching composition in the range from about 10% to about 60%;  
a quantity of glycerine having a weight percent of the dental bleaching composition in the range from about 20% to about 70%;  
30 a quantity of carboxypolymethylene having a weight percent of the dental bleaching composition in the range from about 3.5% to about 12%; and  
a sufficient quantity of a base to adjust the pH of the dental bleaching composition to within the pH  
35 range from about 5 to about 7.

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11. A dental bleaching composition as defined in claim 10, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

10

12. A dental bleaching composition as defined in claim 10, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

15

13. A dental bleaching composition as defined in claim 10, wherein the dental bleaching agent comprises hydrogen peroxide in the range from about 2% to about 10% by weight of the dental bleaching composition.

20

14. A dental bleaching composition as defined in claim 10, wherein the quantity of water has a weight percent of the total dental bleaching composition in the range from about 15% to about 40%.

25

15. A dental bleaching composition as defined in claim 10, wherein the quantity of glycerine has a weight percent of the dental bleaching composition in the range from about 40% to about 60%.

30

16. A dental bleaching composition as defined in claim 10, wherein the quantity of carboxypolymethylene has a weight percent of the dental bleaching composition in the range from about 4.5% to about 10%.

35

17. A dental bleaching composition as defined in claim 10, wherein the quantity of carboxypolymethylene has

1 a weight percent of the dental bleaching composition in the  
range form about 6% to about 8%.

5 18. A dental bleaching composition as defined in  
claim 10, wherein the quantity of carboxypolymethylene has  
a weight percent in the range from about 15% to about 35%  
by weight of the total quantity of water in the total  
dental bleaching composition.

10 19. A dental bleaching composition as defined in  
claim 10, wherein the quantity of carboxypolymethylene has  
a weight percent in the range from about 20% to about 30%  
by weight of the total quantity of water in the total  
15 dental bleaching composition.

20 20. A dental bleaching composition as defined in  
claim 10, wherein the carboxypolymethylene comprises a  
pharmaceutical grade carboxypolymethylene.

20 21. A dental bleaching composition as defined in  
claim 10, wherein the dental bleaching composition is  
dispensed in unit dosage quantities.

25 22. A method for bleaching a patient's teeth  
comprising:

(a) obtaining a dental tray configured to cover  
a patient's teeth surfaces to be bleached and  
configured to hold a quantity of dental bleaching  
composition;

30 (b) placing a quantity of dental bleaching  
composition within the dental tray, said dental  
bleaching composition comprising:

1 a quantity of dental bleaching agent capable  
of bleaching vital tooth surfaces in contact with  
said dental bleaching agent; and

5 a matrix material into which the dental  
bleaching agent is dispersed, said matrix  
material including carboxypolymethylene in the  
range from about 3.5% to about 12% by weight of  
the dental bleaching composition;

10 (c) positioning the dental tray over the  
patient's teeth surfaces such that a portion of the  
dental bleaching composition is in contact with the  
patient's teeth surfaces to be bleached;

15 (d) allowing the dental tray to remain  
positioned over the patient's teeth surfaces; and

(e) removing the dental tray from the patient's  
teeth.

20 23. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the step of obtaining a dental  
tray further comprises obtaining a dental tray constructed  
with reservoirs for holding additional dental bleaching  
composition such that when the dental tray is positioned  
25 over the patient's teeth surfaces, the additional dental  
bleaching composition within the reservoirs is in contact  
with the patient's teeth surfaces to be bleached.

30 24. A method for bleaching a patient's teeth as  
defined in claim 22, further comprising the step of  
repeating steps (b) through (e).

35 25. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the quantity of dental  
bleaching composition placed within the dental tray  
includes a matrix material comprising carboxypolymethylene

1 in the range from about 4.5% to about 10% by weight of the  
dental bleaching composition.

5 26. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the quantity of dental  
bleaching composition placed within the dental tray  
includes a matrix material comprising carboxypolymethylene  
10 in the range from about 6% to about 8% by weight of the  
dental bleaching composition.

15 27. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the quantity of dental  
bleaching composition placed within the dental tray  
includes a matrix material comprising carboxypolymethylene  
in the range from about 15% to about 35% by weight of the  
total quantity of water in the total dental bleaching  
composition.

20 28. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the quantity of dental  
bleaching composition placed within the dental tray  
includes a matrix material comprising carboxypolymethylene  
in the range from about 20% to about 30% by weight of the  
25 total quantity of water in the total dental bleaching  
composition.

30 29. A method for bleaching a patient's teeth as  
defined in claim 22, wherein the quantity of dental  
bleaching composition placed within the dental tray  
includes a carbamide peroxide as the dental bleaching agent  
in the range from about 3% to about 20% by weight of the  
dental bleaching composition.

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30. A method for bleaching a patient's teeth as defined in claim 22, wherein the quantity of dental bleaching composition placed within the dental tray includes a carbamide peroxide as the dental bleaching agent in the range from about 4% to about 15% by weight of the dental bleaching composition.

10

31. A method for bleaching a patient's teeth as defined in claim 22, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 3 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

15

20

32. A method for bleaching a patient's teeth as defined in claim 22, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 5 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

25

33. A method for bleaching a patient's teeth as defined in claim 22, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 8 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

30

34. A method for bleaching a patient's teeth as defined in claim 22, wherein the quantity of dental bleaching composition placed within the dental tray is sufficiently tacky to retain the dental tray positioned against the patient's teeth surfaces.

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35. A method for bleaching a patient's teeth as defined in claim 22, wherein the quantity of dental bleaching composition placed within the dental tray becomes firmer upon contact with saliva.

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36. A method for bleaching a patient's teeth as defined in claim 22, wherein during the positioning step, a portion of the dental bleaching composition extends to the edge of the dental tray and forms a seal upon contact with saliva.

15

37. A dental tray for delivering a dental agent to a patient's teeth surfaces comprising a synthetic mold of a patient's teeth having constructed therein at least one reservoir for holding a quantity of dental agent adjacent a patient's teeth surfaces.

20

38. A dental tray as defined in claim 37, further comprising a plurality of reservoirs constructed in the dental tray for holding the dental agent adjacent teeth surfaces where the greatest whitening is desired.

25

39. A dental tray as defined in claim 37, wherein the plurality of reservoirs are constructed in the dental tray so as to cover the labial aspect of the patient's teeth.

30

40. A dental tray as defined in claim 37, wherein the synthetic mold comprises a soft vinyl polymeric material having a preformed thickness in the range from about 0.04 inches to about 0.06 inches.

35

41. A method for preparing a dental tray for use in delivering a dental agent to a patient's teeth surfaces comprising the steps of:

1

(a) obtaining an impression of a patient's teeth to be treated with a dental agent;

5

(b) preparing a stone cast of the patient's teeth from said impression;

10

(c) coating selected surfaces of the stone cast of the patient's teeth with a rigid material, said coating being kept a distance greater than about 1 mm from the gingival margin represented on the stone cast;

15

(d) vacuum forming a dental tray from the stone cast using a soft polymeric material; and

(e) trimming the polymeric material such that the polymeric material is kept a distance greater than about 1/4 mm from the gingival margin represented on the stone cast.

20

42. A method for preparing a dental tray as defined in claim 41, wherein the soft polymeric material comprises a soft vinyl material having a preformed thickness in the range from about 0.04 inches to about 0.06 inches.

25

43. A method for manufacturing a sustained release dental bleaching composition comprising the steps of:

(a) dissolving a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with said dental bleaching agent in a quantity of water;

30

(b) mixing a quantity of carboxypolymethylene having a weight percent of the total dental bleaching composition in the range from about 3.5% to about 12% with a quantity of glycerine having a weight percent of the total dental bleaching composition in the range from about 20% to about 70%, thereby forming a carboxypoly-methylene/glycerine mixture;

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(c) quickly dispersing said carboxypolymethylene/ glycerine mixture into the quantity of water, thereby forming a sustained release dental bleaching composition; and

5

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(d) adding a sufficient quantity of a base to the dental bleaching composition to adjust the pH of the dental bleaching composition to within the pH range from about 5 to about 7 and such that the total quantity of water in the final dental bleaching composition has a weight percent in the range from about 10% to about 60%.

15

44. A method for manufacturing a sustained release dental bleaching composition as defined in claim 43, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

20

45. A method for manufacturing a sustained release dental bleaching composition as defined in claim 43, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

25

30

46. A method for manufacturing a sustained release dental bleaching composition as defined in claim 43, wherein the total quantity of water in the final dental bleaching composition has a weight percent in the range from about 15% to about 40%.

35

47. A method for manufacturing a sustained release dental bleaching composition as defined in claim 43, wherein the quantity of glycerine has a weight percent of

1 the dental bleaching composition in the range from about  
30% to about 60%.

5 48. A method for manufacturing a sustained release  
dental bleaching composition as defined in claim 43,  
wherein the quantity of carboxypolymethylene has a weight  
percent of the dental bleaching composition in the range  
from about 4.5% to about 10%.

10 49. A method for manufacturing a sustained release  
dental bleaching composition as defined in claim 43,  
wherein the carboxypolymethylene comprises a pharmaceutical  
grade carboxypolymethylene.

15 50. A sustained release anticariogenic dental  
composition comprising:

a quantity of anticariogenic agent capable of  
treating vital tooth surfaces in contact with said  
anticariogenic agent; and

20 a matrix material into which the anticariogenic  
agent is dispersed, said matrix material having a  
sufficiently high viscosity and low solubility in  
saliva such that the matrix material provides  
25 sustained release of the anticariogenic agent to vital  
tooth surfaces, said matrix material comprising  
carboxypolymethylene in the range from about 3.5% to  
about 12% by weight of the dental composition, said  
matrix material further comprising a sufficient  
30 quantity of base to adjust the pH of the dental  
composition to within the pH range from about 5 to  
about 7.

35 51. A sustained release anticariogenic dental  
composition as defined in claim 50, wherein the

1 anticariogenic agent comprises sodium fluoride in the range  
from about 1% to about 5% by weight of the dental  
composition.

5 52. A sustained release antimicrobial dental  
composition comprising:

10 a quantity of antimicrobial dental agent capable  
of treating dental tissues in contact with said  
antimicrobial agent; and

15 a matrix material into which the antimicrobial  
dental agent is dispersed, said matrix material having  
a sufficiently high viscosity and low solubility in  
saliva such that the matrix material provides  
sustained release of the antimicrobial dental agent to  
dental tissues, said matrix material comprising  
20 carboxypolymethylene in the range from about 3.5% to  
about 12% by weight of the dental composition, said  
matrix material further comprising a sufficient  
quantity of base to adjust the pH of the dental  
composition to within the pH range from about 5 to  
about 7.

25 53. A sustained release antimicrobial dental  
composition as defined in claim 52, wherein the  
antimicrobial dental agent comprises chlorhexidine  
gluconate.

30 54. A sustained release antimicrobial dental  
composition as defined in claim 52, wherein the  
antimicrobial dental agent comprises tetracycline.

35 55. A sustained release antimicrobial dental  
composition as defined in claim 52, wherein the

1 antimicrobial dental agent is capable of treating  
periodontal pockets.

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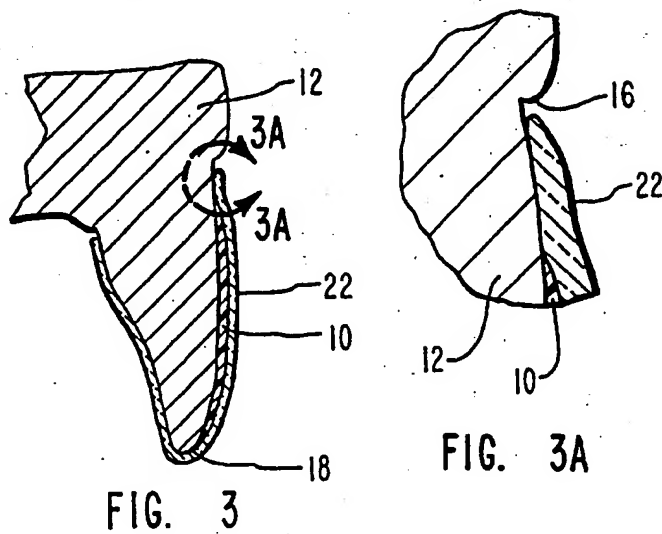
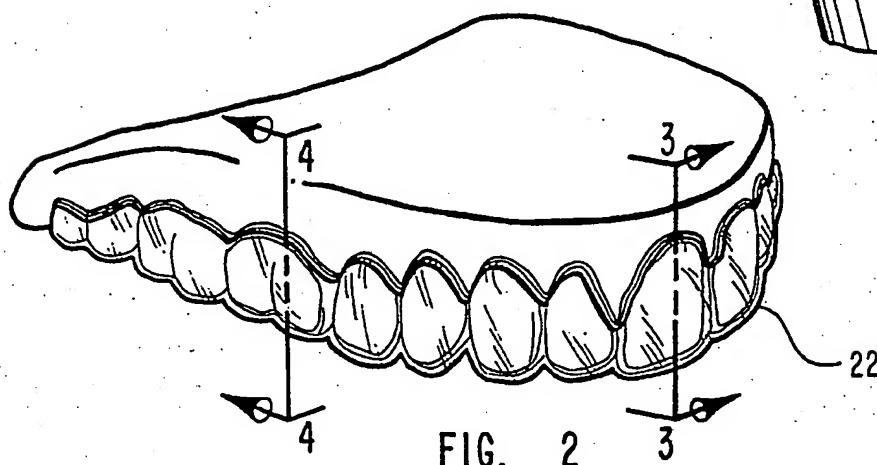
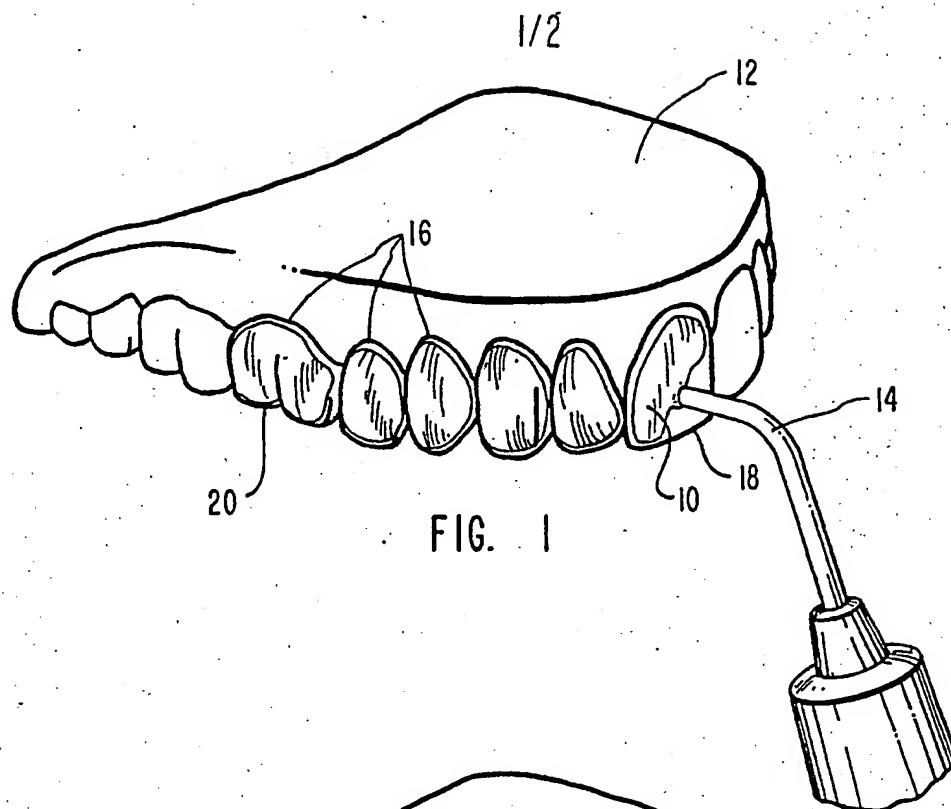
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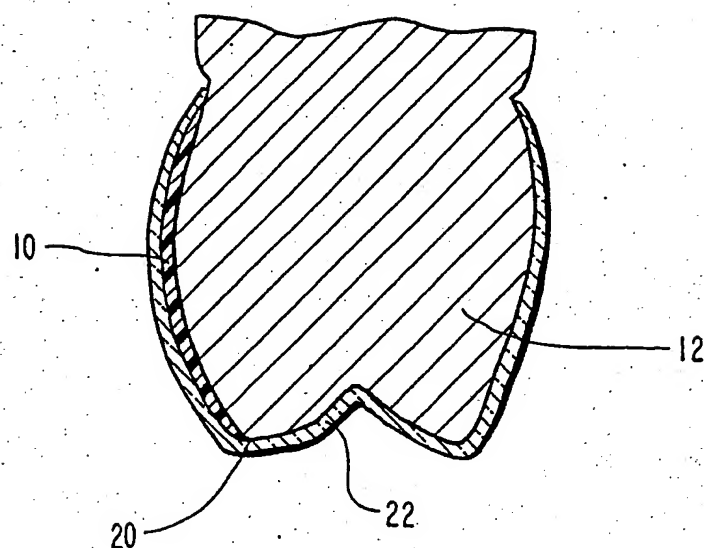


FIG. 4

## BLEACHING EFFECT OF 10% CARBAMIDE PEROXIDE GELS.

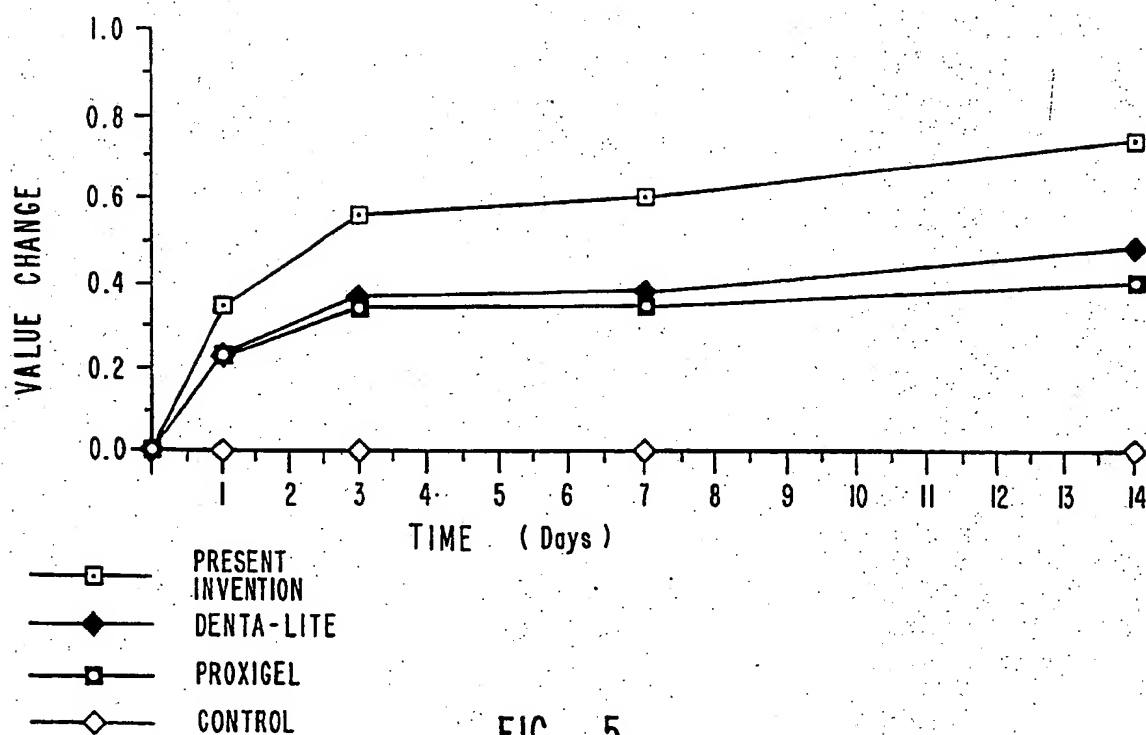


FIG. 5

# INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US91/01794**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup> According to International Patent Classification (IPC) or to both National Classification and IPC <b>INT. CL.5 CO1B 15/00</b> <b>U.S. CL. 252/186.27</b>																				
<b>II. FIELDS SEARCHED</b> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched <sup>7</sup></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border: 1px solid black; text-align: left;">Classification System</th> <th style="border: 1px solid black; text-align: left;">Classification Symbols</th> </tr> <tr> <td style="border: 1px solid black; vertical-align: top; padding: 5px;">U.S.</td> <td style="border: 1px solid black; vertical-align: top; padding: 5px;">252/186.27, 186.28, 186.29 106/35</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>8</sup></div>			Classification System	Classification Symbols	U.S.	252/186.27, 186.28, 186.29 106/35														
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<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border: 1px solid black; text-align: left;">Category <sup>*</sup></th> <th style="width: 60%; border: 1px solid black; text-align: left;">Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup></th> <th style="width: 30%; border: 1px solid black; text-align: left;">Relevant to Claim No. <sup>13</sup></th> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">X Y</td> <td style="border: 1px solid black; vertical-align: top;">US, A, 3,657,413 Published 18 April 1972 Rosenthal (Columns 3-4)</td> <td style="border: 1px solid black; vertical-align: top;">1-21,43-49 22-36</td> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">X Y</td> <td style="border: 1px solid black; vertical-align: top;">US, A, 3,499,844 Published 10 March 1970 Kibbel (Column 2-3)</td> <td style="border: 1px solid black; vertical-align: top;">1-21,43-49 22-36</td> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">Y</td> <td style="border: 1px solid black; vertical-align: top;">US, A, 4,839,157 Published 13 June 1989 Mel-King ng et al. (Abstract)</td> <td style="border: 1px solid black; vertical-align: top;">1-36, 43-49</td> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">Y</td> <td style="border: 1px solid black; vertical-align: top;">US, A, 4,518,721 Published 21 May 1985 Dhabhar et al.</td> <td style="border: 1px solid black; vertical-align: top;">1-36,43-49</td> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">A</td> <td style="border: 1px solid black; vertical-align: top;">US, A, 4,032,627 Published 28 JUNE 1977</td> <td style="border: 1px solid black;"></td> </tr> </table>			Category <sup>*</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>	X Y	US, A, 3,657,413 Published 18 April 1972 Rosenthal (Columns 3-4)	1-21,43-49 22-36	X Y	US, A, 3,499,844 Published 10 March 1970 Kibbel (Column 2-3)	1-21,43-49 22-36	Y	US, A, 4,839,157 Published 13 June 1989 Mel-King ng et al. (Abstract)	1-36, 43-49	Y	US, A, 4,518,721 Published 21 May 1985 Dhabhar et al.	1-36,43-49	A	US, A, 4,032,627 Published 28 JUNE 1977	
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>*</sup> Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>																				
<b>IV. CERTIFICATION</b> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border: 1px solid black; vertical-align: top; padding: 5px;">           Date of the Actual Completion of the International Search   <b>08 JULY 1991</b> </td> <td style="width: 50%; border: 1px solid black; vertical-align: top; padding: 5px;">           Date of Mailing of this International Search Report   <b>22 JUL 1991</b> </td> </tr> <tr> <td style="border: 1px solid black; vertical-align: top; padding: 5px;">           International Searching Authority   <b>ISA/US</b> </td> <td style="border: 1px solid black; vertical-align: top; padding: 5px;">           Signature of Authorized Officer  <b>JOSEPH D. ANTHONY</b>  <i>Arguth Newyer</i> </td> </tr> </table>			Date of the Actual Completion of the International Search  <b>08 JULY 1991</b>	Date of Mailing of this International Search Report  <b>22 JUL 1991</b>	International Searching Authority  <b>ISA/US</b>	Signature of Authorized Officer <b>JOSEPH D. ANTHONY</b> <i>Arguth Newyer</i>														
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## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE <sup>1</sup>

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers \_\_\_\_\_, because they relate to subject matter <sup>12</sup> not required to be searched by this Authority, namely:
2. ☐ Claim numbers \_\_\_\_\_, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out <sup>13</sup>, specifically:
3. ☐ Claim numbers \_\_\_\_\_, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING <sup>2</sup>

This International Searching Authority found multiple inventions in this international application as follows:

(See attachment)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:  
1-36 AND 43-49
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.



ATTACHMENT TO PART VI: OBSERVATIONS WHERE UNITY OF  
INVENTION IS LACKING

- GROUP I: Claims 1-36 and 43-49 drawn to a product (a dental bleaching agent), a use of the product (a method for bleaching a patient's teeth), and a process of making the product (a method for manufacturing a sustained release dental bleaching composition).
- GROUP II: Claims 37-42 drawn to a product (a dental tray) and a process of making the product (a method for preparing a dental tray) thereby consisting of a combination.
- GROUP III: Claims 50 and 51 drawn to a product (a sustained release anticariogenic dental composition).
- GROUP IV: Claims 52-55 drawn to a product (a sustained release antimicrobial dental composition).

